

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: INSULIN PRICING
LITIGATION**

Case No. 2:23-md-3080 (BRM)(RLS)

MDL No. 3080

This Document Relates to:

*The State of Mississippi, ex rel. Lynn
Fitch, Attorney General v. Eli Lilly and
Company, et al.*

Case No. 2:23-cv-04364 (BRM)(RLS)

**DECLARATION OF ANDREW YAPHE
IN SUPPORT OF MANUFACTURER DEFENDANTS'
MOTION FOR JUDGMENT ON THE PLEADINGS**

I, Andrew Yappe, hereby declare as follows:

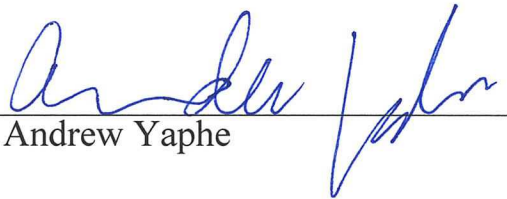
1. I am an attorney with the law firm Davis Polk & Wardwell LLP, counsel for defendant Novo Nordisk Inc. in the above-captioned matter, licensed to practice law in the State of California and admitted to this Court *pro hac vice*.

2. On behalf of Defendants Eli Lilly and Company, Novo Nordisk Inc., and Sanofi-Aventis U.S. LLC (collectively, "Manufacturers"), I submit this Declaration in support of Manufacturer Defendants' Motion for Judgment on the Pleadings.

3. Attached hereto as Exhibit 1 is a true and correct excerpted copy of the United States Senate Committee on Finance staff report, titled “Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,” published on January 14, 2021, *full text available online at* [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf).

I declare under penalty of perjury that the foregoing is true and correct.

Executed on June 5, 2024 at Menlo Park, CA.



Andrew Yaphe

EXHIBIT 1

United States Senate
Senate Finance Committee

Charles E. Grassley, Chairman
Ron Wyden, Ranking Member

Insulin:

Examining the Factors Driving the Rising Cost of a Century Old Drug

Staff Report



Table of Contents

I. Introduction	4
II. Key Findings	6
a. Diabetes: The Disease.....	11
b. How the High Cost of Insulin Negatively Affects Individuals with Diabetes.....	13
II. Examining the Flow of Goods and Money in the U.S. Pharmaceutical Supply Chain .	15
a. Drug Manufacturers	16
i. Research & Development, Sales & Marketing	17
b. Wholesale Distributors and Pharmacies	23
c. Health Insurance	24
i. Medicare Part D	25
ii. Medicaid Drug Rebate Program.....	27
iii. Employer-sponsored health insurance	28
d. The PBM Industry.....	28
i. Formulary Development Process	34
ii. Rebates, Discounts, and Other Fees	38
III. The Cost of Insulin to Patients, Medicare, and Private Payers	41
a. Insulin List and Net Price Trends: 2013 to 2019	42
b. Medicare Part D’s Pre-Rebate Spending on Insulin has Risen Steadily Since 2010.....	46
c. Patient Out-of-Pocket Spending in Medicare Part D	48
d. A Case Study: Examining Sanofi and Novo Nordisk’s Decision to Implement Aggressive List Price Increases and the Impact on the Long-acting Insulin Market.....	49
i. In 2014, Novo Nordisk Engaged in Shadow Pricing to Respond to Sanofi’s 2013 Pricing Actions	52
ii. In 2015, Novo Nordisk Ended its Shadow Pricing Strategy to Set Up a New Basal Insulin Therapy, Tresiba.....	56
iii. In 2017 and 2018, Novo Nordisk Resumed Shadow Pricing to Respond to Sanofi’s Pricing Actions	59
iv. In 2018, Novo Nordisk Discussed List Price Decreases after Feeling Outside Pressure	61
e. Beyond Long-Acting Insulin: Companies Used Shadow Pricing Across Multiple Product Lines	63
IV. Rebates, Administrative Fees and Other Common Contract Provisions Related to Insulin WAC and Other Therapies	65
a. Rebates for Insulins Have Increased Exponentially Since 2013	66

i. Rebates Vary Widely by Payer	69
b. PBM Contracting Practices May Contribute to High Rebates and High List Prices in the Insulin Therapeutic Class	70
i. Use of Exclusion Lists.....	71
ii. Administrative Fees.....	80
iii. Price Protection Clauses.....	84
V. Conclusion	88
Appendix.....	90

According to internal memoranda prepared for Eli Lilly's executive committee, in November 2016, the company assumed its "core insulins" would earn revenue of \$3.3 billion in 2017 (\$4 billion worldwide).⁶⁶ In order to achieve these results, Eli Lilly sought to improve its competitive position with respect to its key brands and planned to devote a majority of its R&D spending on clinical trials for existing Type 2 diabetes drugs—Jardiance,⁶⁷ Tranjenta,⁶⁸ and Trulicity⁶⁹—the last of which was Eli Lilly's "largest growth driver."⁷⁰ Indeed, according to Eli Lilly, "Trulicity has been a catalyst . . . with growth driven by investments in [direct to consumer], sales force reach, and access."⁷¹ These post-marketing clinical trials were intended to show that the therapy helped reduce incidence of cardiovascular disease which allowed Eli Lilly to seek an expansion of its FDA label indication.⁷² However, even with these significant studies, the company's R&D spending for its entire diabetes franchise was budgeted to be just one-third of its sales, goods and administrative expenses, and, in fact, less than the cost of a single line item—Eli Lilly's global diabetes salesforce.⁷³ The following table details Eli Lilly's funded initiatives and sales force spending between 2017 and 2018.⁷⁴

⁶⁶ LLY-SFCOM-UR-00006920; LLY-SFCOM-UR-00006921; LLY-SFCOM-UR-00006924, at LLY-SFCOM-UR-00006925.

⁶⁷ Press Release, Eli Lilly, Jardiance meets primary endpoint in reducing risk of cardiovascular death or hospitalization for heart failure in phase III clinical trial in adults with and without diabetes (July 2020), <https://investor.lilly.com/news-releases/news-release-details/jardiance-meets-primary-endpoint-reducing-risk-cardiovascular>.

⁶⁸ Press Release, Eli Lilly, Boehringer Ingelheim and Lilly full results of Tradjenta's CARMELINA cardiovascular outcome trial (Oct. 4, 2018), <https://investor.lilly.com/news-releases/news-release-details/boehringer-ingelheim-and-lilly-present-full-results-tradjentas>.

⁶⁹ Press Release, Eli Lilly, Trulicity significantly reduced major cardiovascular events for broad range of people with type 2 diabetes (Jul. 9, 2019), <https://investor.lilly.com/news-releases/news-release-details/trulicity-dulaglutide-significantly-reduced-major>.

⁷⁰ LLY-SFCOM-UR-00006924, at LLY-SFCOM-UR-00006952.

⁷¹ LLY-SFCOM-UR-00006921, at LLY-SFCOM-UR-00006922. Trulicity, Jardiance and Trajenta are marketed and manufactured in partnership with Boehringer Ingelheim.

⁷² For example, in February 2020, Eli Lilly announced that the FDA approved Trulicity for the reduction of major adverse cardiovascular events in adults with type 2 diabetes. According to Eli Lilly, this new indication makes Trulicity the only type 2 medicine approved to reduce these risks. See Press Release, Eli Lilly, Trulicity is the first and only type 2 diabetes medicine approved to reduce cardiovascular events in adults with and without established cardiovascular disease (Feb. 21, 2020), <https://investor.lilly.com/news-releases/news-release-details/trulicity-dulaglutide-first-and-only-type-2-diabetes-medicine>. LLY-SFCOM-UR-00006921; LLY-SFCOM-UR-00006924, at LLY-SFCOM-UR-00006952.

⁷³ LLY-SFCOM-00000045; LLY-SFCOM-00002499; LLY-SFCOM-UR-00006921; LLY-SFCOM-UR-00006924, at LLY-SFCOM-UR-00006952.

⁷⁴ LLY-SFCOM-UR-00006924, at LLY-SFCOM-UR-00006952.

Funded Initiatives

SG&A			
Funded Priorities - Total Spend for Each Item/Initiative included in Add-up while achieving Target			
Priority Level			
2017	2018	A/B/C	
294	298	A	Competitive investment in Trulicity to deliver ~\$1bn in YOY BAC growth; includes DTC [2017: \$140m and 2018: \$142m]
118	113	A	Prepare to capitalize on Jardiance CV label outcome
97	100	A	Retain and protect the \$3.3bn insulin franchise [DBU markets]
22	22	A	Capitalize on Humulin U500 KwikPen launch uptake
22	32	A	Pre-launch investment in Nasal Glucagon and Connected Care [US and Global]
116	116	A	Regional / Global initiatives - marketing, communications, strategy, operations, market research, admin, evolution
712	738	A	Diabetes Salesforce [2017 values - US: \$423m; EUCAN: \$180m; Japan: \$109m]
49	49	B	Optimize Basaglar investment
41	42	B	Non-Branded HCP, Consumer and Payer Initiatives
28	27	C	Trajenta SG&A - aligned investment with BI [23% SG&A/Sales delivering ~\$400m in Revenue (LLY share)]
55	41		Pharma Fee all products - Fixed
1584	1609		SG&A Total

R&D			
Funded Priorities - Total Spend for Each Item/Initiative included in Add-up while achieving Target			
Priority Level			
2017	2018	A/B/C	
140	118	A	Trulicity REWIND extension, high dose Ph2 study, and Pediatric study
89	61	A	Jardiance heart failure, Japan safety and efficacy studies, Type 1 DM, post-marketing
88	87	A	Global Medical
59	54	A	Trajenta CVOT (CAROLINA and CARMELINA), pediatric, add-on to basal
43	32	A	Insulins; partnership with Insulet; device updates; Humulin U500
22	43	A	Nasal Glucagon; includes milestone in 2018
122	152	B	Corp Development Multi-Molecule/Non-Molecule
10	8	B	Basaglar U200 and China
4	0	B	DNR-free vial stoppers - Humalog and Humulin
3	8	C	Other Development initiatives
3	0	C	PCSK9 Phase 3 enabling
-41	-40	C	Admin Objective
542	522		R&D Total

29

2. Sanofi

In response to the Committee's request, Sanofi estimated that it had invested approximately \$4.5 billion in diabetes, which includes both insulin and non-insulin products, between 2012 and 2018, noting that it spent \$800 million in 2018 on diabetes alone.⁷⁵ Sanofi only provided R&D product-specific data for 2014 to 2018, and limited the data to five insulin products.⁷⁶ Therefore, the Committee was unable to confirm Sanofi's total R&D spending on its diabetes franchises. However, R&D spending (which was reported to the Committee in dollars) on these five diabetes products accounted for a fraction of the company's reported revenue from its diabetes franchise, as reported to the U.S. Securities and Exchange Commission.⁷⁷ From 2014 to 2018, the company's diabetes franchise generated nearly €31 billion in net sales

⁷⁵ Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019).

⁷⁶ Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 29, 2019).

⁷⁷ *Id.* Sanofi produced data regarding gross sales, net sales, and gross units by product line, which is how Sanofi tracks this information. *Id.*

(approximately \$37 billion based on current currency conversion rates),⁷⁸ whereas R&D spending for these five insulin products was approximately \$902 million.⁷⁹

Net Sales of Sanofi Diabetes Products in Millions of Euros (2014-2018)						
	2014	2015	2016	2017	2018	Total
Admelog					€ 93	€ 93
Apidra	€ 336	€ 376	€ 367	€ 286	€ 357	€ 1,722
Lantus	€ 6,344	€ 6,390	€ 5,714	€ 4,761	€ 3,565	€ 26,774
Soliqua					€ 73	€ 73
Toujeo		€ 164	€ 649	€ 630	€ 840	€ 2,283
Total	€ 6,680	€ 6,930	€ 6,730	€ 5,677	€ 4,928	€ 30,945

Source: Securities and Exchange Commission. According to Sanofi, “[n]et sales comprise revenue from sales of pharmaceutical products, consumer healthcare products, active ingredients and vaccines, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities.” (Sanofi, 20-F, 2019)

Sanofi R&D Spending by Product in Millions of Dollars (2014-2018)						
	2014	2015	2016	2017	2018	Total
Admelog	\$ 24.45	\$ 54.53	\$ 38.25	\$ 11.26	\$ 6.15	\$ 134.64
Apidra	\$ 2.31	\$ 5.47	\$ 3.64	\$ 1.36	\$ 1.04	\$ 13.82
Lantus	\$ 42.79	\$ 21.95	\$ 20.76	\$ 16.44	\$ 8.24	\$ 110.18
Soliqua	\$ -	\$ 1.03	\$ 40.94	\$ 70.76	\$ 68.74	\$ 181.47
Toujeo	\$ 67.53	\$ 72.45	\$ 150.25	\$ 117.84	\$ 54.43	\$ 462.50
Total	\$ 137.08	\$ 155.43	\$ 253.84	\$ 217.66	\$ 138.60	\$ 902.61

Source: Letter to Senator Grassley and Senator Wyden from Jeffrey Handwerker, Counsel, Sanofi (March 29, 2019).

3. Novo Nordisk

Novo Nordisk failed to provide a detailed accounting of its R&D expenditures to the Committee. However, on its annual report submitted to the SEC, the company reported that it spent approximately 36 million Danish krone related to diabetes and obesity R&D between 2017 and 2019.⁸⁰

b. Wholesale Distributors and Pharmacies

Drugs are purchased directly by wholesale distributors and delivered to a variety of customers, including pharmacies, physicians, hospitals, and other medical facilities. Wholesale distributors negotiate with drug manufacturers for discounts off a drug’s list price, often referred

⁷⁸ Sanofi reported net sales in Euros to the Securities and Exchange Commission.

⁷⁹ *Id.*

⁸⁰ See *Novo Nordisk Annual Report 2019*, NOVO NORDISK at 52 (2019), <https://www.novonordisk.com/content/dam/nncorp/global/en/annual-report/pdfs/2019/Novo-Nordisk-Annual-Report-2019.pdf>.